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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,425	02/19/2002	Harold G. Brown	2059-0103P	1812

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EXAMINER	
UNDERDAHL, THANE E	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
02/26/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	09/890,425	BROWN ET AL.	
	Examiner	Art Unit	
	THANE UNDERDAHL	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2008*.

2a)☒ This action is FINAL. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *24-27, 30, 32-35, 52, 97-111,116* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 114, 115, and 117-130* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 7, 11, 12, 14, 19, 22-27, 30, 32-35, 36, 37, 41, 42, 46-48, 51-54, 59, 66, 69, 70, 72-94, 97-115-130.

Detailed Action

This Office Action is in response to the Applicant's reply received 4/25/08. Claims 7, 11, 12, 14, 19, 22-27, 30, 32-35, 36, 37, 41, 42, 46-48, 51-54, 59, 66, 69, 70, 72-94, 97-115-130 are pending. Claims 24-27, 30, 32-35, 52, 97-111,116 are withdrawn. Claims 129 and 130 are new.

Response to Applicant's Arguments

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of claims 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 114, 115, and 117-128 over Della Valle et al. (U.S. Patent # 4736024) and further in view of Balazs (U.S. Patent # 4,141973) were considered but not found persuasive.

The Applicant argues that HA is not an "active ingredient" but is a carrier in the composition of Della Valle et al. However the term "active ingredient" is broad and the specification does not limit the definition or the "activity" the ingredient imparts. Indeed the activity of a chemical compound in a composition is inherent in said compounds structure (M.P.E.P. § 2112.01 I and II) and as such since the art reads on the claimed chemical compound it also reads on the inherent properties of this compound (M.P.E.P. § 2112 IV and V). Indeed Della Valle et al. teach that HA does indeed have activity since HA has "been used...as therapeutic, auxiliary and substitutive agents for natural organs and tissues" (Della Valle, col 5, lines 41-42).

The Applicant argues that is not considered as an active ingredient HA by Della Valle et al. and that it is used as a carrier. The Applicant argues that the claims exclude it as a carrier. However, HA may indeed serve as a carrier but as previously mentioned it is also inherently an active ingredient. Della Valle et al. also teach that their HA composition can be diluted with common carriers such as saline (Della Valle, col 8, lines 30-35). Furthermore, since Della Valle et al. teach expressly teach that their composition can be formulated into a nasal spray for inhalation in the oral cavity and pharynx, (Della Valle, col 5, lines 5 and 6) Della Valle et al. reads on carriers such as "a vaporizer liquid".

The Applicant argues that Della Valle et al. teaches away from using the HA of Balazs et al. It is acknowledged that the prior art as a whole must suggest the desirability of the invention, but a finding that the prior art as a whole suggests the desirability of a particular combination need not be supported by a finding that the prior art suggest that the combination claimed is the preferred, or most desirable combination. The prior art's mere disclosure of more than one alternative does not constitute a teaching away from the claimed invention because such disclosure does not criticize, discredit, or other wise discourage the solution claimed in the patent application. See In re Fulton, 391 F.3d 1195, 73 USPQ2d 1411 (2004). Indeed Della Valle et al. cites Balazs et al. as an example of how to obtain HA (Della Valle, col 6, lines 10-15) and never discourages one of ordinary skill in the art against using the methods of Balazs et al.

Furthermore Della Valle et al. teaches that the molecular weight ranges for their invention is 30,000 to 13 million (Della Valle et al. col 6, lines 35-40) which encompasses the molecular weight of 750,000 to 1.2 million taught by Balazs (Balazs, col 4, lines 40-50). It would be obvious to one of ordinary skill in the art that since both compositions use HA and that the structure of HA for each composition is the same then indeed they will have the same properties as well as function and as such it would be obvious to substitute the HA of Balazs et al. with that of Della Valla et al. and achieve the same results for their composition ((KSR International v. Teleflex Inc. 550 U.S. ___, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007)).

Finally the arguments that the HA of Balazs et al. is too pure to be used in the composition of Della Valle et al. were considered but found not persuasive. Indeed both Balazs et al. and Della Valle et al. were used in the process of wound healing (Della Valle et al. col 27, line 4 and Balazs et al. col 15, example 3) therefor their use of HA is for a common purpose and as such obvious to substitute one for the other (M.P.E.P. § 2144.06 and (KSR International v. Teleflex Inc. 550 U.S. ___, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007)))

Therefor the rejection stands and is repeated below and applied to new claims 129 and 130.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 114, 115, and 117-130 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Della Valle et al. (U.S. Patent # 4736024) and further in view of Balazs (U.S. Patent # 4,141973).

These claims are to a composition of orally ingestible or mucosally absorbable glycosaminoglycan such as hyaluronic acid (hyaluronan or HA) that has at least one fraction with a molecular weight 1,000,000 daltons as measure by the protein standard/intrinsic viscosity. The composition must not contain an essential oil as an active ingredient and contains up to 5% by weight protein contaminants and a carrier selected from several forms such as a vaporizer liquid, spray, cream, ointment, drink or drink mix. The composition may also contain a second glycosaminoglycan fraction from weighing from 1,000 to less than 50,000 daltons and 100,000 to 300,000 daltons. The composition contains less than 98% HA.

Claims 54, 113 and 123 recite an intended use and a method step for their respective compositions. These intended uses do not impart a structural relationship, such as an additional component, to the composition (M.P.E.P. § 2111.02 II). Since compositions are defined and limited by their components, these limitations are not further limiting.

Della Valle et al. teach a composition that may have fractions of HA from ~11 million to 30,000 (Della Valle, col 6, lines 1-10) for applications in human and veterinary medicine (Della Valle, col 2, lines 57-60) that is absent and essential oil as the active

ingredient. This composition can be formulated into preparation for adsorption through the mucus membranes (Della Valle, col 5, lines 3-5) such as nasal sprays or oral inhalers or even gels and ointments with, pain-reliever (analgesic) anti-biotic and anti-inflammatory properties (Della Valle, col 3 and 4, entire section, specifically col 3, lines 25-35 and Examples 1-19). Since the HA can be applied orally or nasally it would have been obvious to someone skilled in the art that that HA is of at least food grade purity. Della Valle lists multiple ranges for the HA in their composition from 13 million to 30,000 as well as 50,000 to about 100,000. The amount of HA in their many compositions can vary greatly with some examples showing 34.0% and 80.0% HA (Della Valle, Example 2 and 5).

What Della Valle et al. does not teach is that the HA is defined by its intrinsic viscosity or by the protein standard. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Balazs. He teach an ultrapure HA that can be made into a 1% optomological solution and does not cause the inflammation of owl monkey eyes (Balazs, see Abstract). His ultrapure solution of HA has a molecular weight of greater than 1,200,000 as measure by intrinsic viscosity (Balazs, col 4, lines 40-50). The HA of Balazs also contains a protein content of less then 0.5% by weight.

It would have been obvious to someone skilled in the art to use the HA of Balazs in the compositions of Della Valle et al. A *prima facie* case can be made since Della Valle et al. directly cites this same patent in their patent (Della Valle et al., see References Cited). Also Della Valle et al. expressly mentions the work of Balazs on the

isolation and use of HA in the specification of their patent (Della Valle et al., col 5, lines 15-45). Therefore one of ordinary skill in the art would be motivated and have a reasonable expectation of success to use the HA of Balazs in the invention of Della Valle et al. Also one of ordinary skill in the art would be motivated to measure their other shorter chain fractions of HA by intrinsic viscosity to make sure the have a common standard of molecular weight between the large and small fractions. Since both Balazs and Della Valle et al. teach the use of HA in the similar molecular weight range it would have been obvious to someone skilled in the art to use the HA characterized by intrinsic viscosity of Balazs in the invention of Della Valle et al since one of ordinary skill in the art would recognize these are art-defined equivalents for the same purpose and have the same predictable result. (M.P.E.P. § 2144.06 and KSR International Co. v. Teleflex Inc., 550 U.S.--, 82 USPQ2d 1385 (2007)).

Also while neither Della Valle and Balazs teach the multiple formulations listed in claims 74-88 such as a gargle, gum, lozenge, foam or capsule they have already taught that the HA compositions are safe for oral, eye and topical application. It would have been obvious to someone skilled in the art to alter their product into these formulations since these are simply well known variations on the formulation for oral and topical administration of compositions.

Therefore the references listed above renders obvious claims 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 114, 115, and 117-130.

In summary no claims, as written, are allowed for this application.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571)

272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
Art Unit 1651

/Leon B Lankford/
Primary Examiner, Art Unit 1651